

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS  
INTERNATIONAL GMBH,  
CEPHALON, LLC, and EAGLE  
PHARMACEUTICALS, INC.,

Plaintiffs,

V.

DR. REDDY'S LABORATORIES,  
LTD. and DR. REDDY'S  
LABORATORIES, INC.,

Defendants.

**C.A. No. 21-695-CFC**  
**ANDA CASE**

## STIPULATION AND [PROPOSED] ORDER

Plaintiffs Teva Pharmaceuticals International GmbH, Cephalon, LLC, and Eagle Pharmaceuticals, Inc. (“Plaintiffs”) and Defendants Dr. Reddy’s Laboratories, Ltd., and Dr. Reddy’s Laboratories, Inc. (collectively, “Defendants”), have agreed to the following stipulation, subject to approval of the Court.

**WHEREAS**, Plaintiffs filed this action for infringement of U.S. Patent Nos. 8,609,707 (“the ’707 patent”), 9,265,831 (“the ’831 patent”), 9,572,796 (“the ’796 patent”), 9,572,797 (“the ’797 patent”), 9,034,908 (“the ’908 patent”), 9,144,568 (“the ’568 patent”), 9,597,397 (“the ’397 patent”), 9,597,398 (“the ’398 patent”), 9,597,399 (“the ’399 patent”), 9,000,021 (“the ’021 patent”), 9,579,384 (“the ’384

patent”), 10,010,533 (“the ’533 patent”), 10,052,385 (“the ’385 patent”), 9,572,887 (“the ’887 patent”) and 11,103,483 (“the ’483 patent”) in connection with Defendants’ New Drug Application, NDA No. 215668 (“DRL’s NDA”), to the U.S. Food and Drug Administration seeking approval to market a generic version of Bendeka® (“DRL’s NDA Products”);

**WHEREAS**, the parties have entered into a stipulation dismissing the ’707, ’831, ’796, ’797, ’908, ’568, ’397, ’398, ’399, ’021, ’384, ’533, and ’385 patents from this action (*see* D.I. 43);

**WHEREAS**, Plaintiffs asserted infringement of specific claims of the patents-in-suit, specifically claims 1-3 and 8-29 of the ’887 patent and claims 8-9 and 11-16 of the ’483 patent;

**WHEREAS**, the parties have entered into a stipulation regarding non-infringement of the claims of the ’483 patent, subject to any appeal of the Court’s judgment in *Eagle Pharmaceuticals, Inc. v. Slayback Pharma LLC*, C.A. No. 21-1256-CFC-JLH (D. Del.), D.I. 117 (*see* D.I. 120);

**WHEREAS**, Defendants have asserted non-infringement of the asserted claims of the ’887 patent;

**WHEREAS**, the parties have met and conferred to narrow the issues for trial.

**NOW THEREFORE**, the parties stipulate and agree as follows, for the purpose of this case only:

1. Defendants consent to the entry of judgment in this action that the submission of DRL's NDA infringes, and use of DRL's NDA Products according to DRL's proposed labeling would infringe, claims 1-3 and 8-29 of the '887 patent, to the extent those claims are asserted by Plaintiffs at trial and are found to be valid and enforceable.

2. Defendants reserve all remaining counterclaims and defenses to the '887 patent, including those related to invalidity of the '887 patent.

3. This Stipulation is not an agreement as to the proper scope of an injunction, if any, or that Plaintiffs are entitled to an injunction against Defendants based on any agreements in this stipulation. For the avoidance of doubt, this stipulation alone does not entitle Plaintiffs to any injunctive relief, including an order pursuant to 35 U.S.C. § 271(e)(4)(A). Plaintiffs expressly reserve the right to seek preliminary or permanent injunctive relief and/or an order pursuant to 35 U.S.C. § 271(e)(4)(A) as part of a final judgment in this action.

4. The Court has construed the terms "non-aqueous liquid composition," "stabilizing amount of an antioxidant," and "providing" (D.I. 98). For the avoidance of doubt, if the Court's claim construction decision with respect to the '887 patent is reversed or vacated, this stipulation will not remain in place and Defendants will be entitled to contest infringement of the asserted claims of the '887 patent. Plaintiffs reserve the right to contest whether such arguments have been adequately preserved.

5. Nothing in this stipulation supersedes or supplants the safe harbor protections of 35 U.S.C. § 271(e)(1) or Defendants' ability to assert and rely on them.

6. Plaintiffs and Defendants specifically reserve the right to appeal any final judgment entered by this Court.

7. Nothing herein shall be construed as an admission that any claim term of the '887 patent is enabled, not lacking in written description, or not indefinite.

8. Should this Stipulation be vacated, nothing herein shall be construed as a waiver by Plaintiffs or Defendants of any claim or defense.

9. Plaintiffs and Defendants reserve all other claims and defenses.

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Dated: January 5, 2023

IT IS SO ORDERED this \_\_\_\_ day of \_\_\_\_\_, 2023.

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Chief United States District Judge